

Form PTO-1449 (modified)

Atty. Docket No.

CLFR:115USC1

Serial No.

10/801,277

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant

Staley A. Brod

Filing Date:

March 16, 2004

Group:

1647

~~1761~~

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
/JS/	A1	4,409,243	10/11/83	Lieb	424	330	11/9/81
	A2	4,462,985	7/31/84	Cummins	424	85	9/7/82
	A3	4,497,795	2/5/85	Cummins	424	85.6	12/13/82
	A4	5,019,382	5/28/91	Cummins	424	85.4	1/17/90
	A5	5,093,338	3/3/92	Byrne	514	291	4/23/91
	A6	5,624,895	4/29/97	Sobel	514	8	2/18/94
	A7	5,780,021	7/14/98	Sobel	424	85.4	3/5/93

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
/JS/	B1	WO 94/20122	9/15/94	WIPO			English
/JS/	B2	WO 96/28183	9/19/96	WIPO			English
/JS/	B3	WO 83/03411	10/13/83	WIPO			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
/JS/	C1	"Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. The IFNB Multiple Sclerosis Study Group," <i>Neurology</i> 43:655-661. 1993.
/JS/	C2	Bayley <i>et al.</i> , "The transmucosal absorption of recombinant human interferon-alpha B/D hybrid in the rat and rabbit," <i>J. Pharm. Pharmacol.</i> 47(9):721-724. 1995.
/JS/	C3	Bocci <i>et al.</i> , "Is interferon effective after oral administration? The state of the art." <i>J. Biol. Regul. Homeos. Agents</i> , 4(2):81-83, 1990.
/JS/	C4	Bocci, "Absorption of cytokines via oropharyngeal-associated lymphoid tissues," <i>Clin Pharmacokinet</i> , 21(6):411-417, 1991.

25503844.1

EXAMINER:

/Jegatheesan Seharaseyon/

DATE CONSIDERED:

03/20/2007

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.



Form PTO-1449 (modified)		Atty. Docket No. CLFR:115USC1	Serial No. 10/801,277
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Staley A. Brod	
		Filing Date: March 16, 2004	Group: 1761 1647
U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 1	Other Art See Page 1	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
/JS/	C5	Bocci, "Immunomodulators as local hormones: new insights regarding their clinical utilization," <i>Journal of Biological Response Modifiers</i> , 4:340-352, 1985.
	C6	Bosio <i>et al.</i> , "Efficacy of low-dose oral use of type I interferon in cytomegalovirus infections in vivo," <i>J. Interferon Cytokine Res.</i> , 19:869-876, 1999.
	C7	Brod and Khan "Oral administration of IFN- α is superior to subcutaneous administration of IFN- α in the suppression of chronic relapsing experimental autoimmune encephalomyelitis," <i>J. Autoimmunity</i> , 9:11-20, 1996.
	C8	Brod <i>et al.</i> , "Ingested (oral) IFN-alpha induces MxA mRNA in RRMS" (Submitted for publication)
	C9	Brod <i>et al.</i> , "Ingested IFN- α has biological effects in humans with relapsing-remitting multiple sclerosis," <i>Mult. Scler.</i> , 3:1-7, 1997.
	C10	Brod <i>et al.</i> , "Ingested interferon α suppresses type I diabetes in non-obese diabetic mice," <i>Diabetologia</i> , 41:1227-1232, 1998.
	C11	Brod <i>et al.</i> , "Ingested interferon alpha induces Mx mRNA," <i>Cytokine</i> , 11:1-8, 1999.
	C12	Brod <i>et al.</i> , "Ingested interferon alpha preserves residual beta cell function type 1 diabetes," <i>J. Interferon Cytokine Res.</i> , 2(12):1021-1030, 2001.
	C13	Brod, "Hypothesis: multiple sclerosis is a type I interferon deficiency syndrome," <i>Proc. Soc. Exp. Biol. Med.</i> 218:278-283, 1998.
	C14	Butcher, "The regulation of lymphocyte traffic," <i>Current Topics in Microbiology and Immunology</i> , 128:85-122, 1986.
	C15	Cantell and Pyhala, "Circulating interferon in rabbits after administration of human interferon by different routes," <i>Virology</i> , 20:97-104, 1973.
	C16	Carter <i>et al.</i> , "Disease modifying therapies in multiple sclerosis," <i>CNS Drugs</i> , 3:99-114, 1995.
	C17	Connelly, "Interferon beta for multiple sclerosis," <i>Ann. Pharmacother.</i> , 28(5):610-616, 1994.
	C18	Dhingra <i>et al.</i> , "A phase-I clinical study of low-dose oral interferon-alpha," <i>J. Immunother.</i> , 14(1):51-55, 1993.
✓	C19	Fleischmann <i>et al.</i> , "Orally administered interferons exert their white blood cell suppressive effects via a novel mechanism," <i>Neurology</i> , 13, 1993.

25503844.1

EXAMINER:

/Jegatheesan Seharaseyana/

DATE CONSIDERED:

03/20/2007

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. CLFR:115USC1	Serial No. 10/801,277
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Staley A. Brod	
		Filing Date: March 16, 2004	Group: 1761 1647
U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 1	Other Art See Page 1	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
/JS/	C20	Gibson <i>et al.</i> , "Pharmacokinetics of recombinant leukocyte A interferon following various routes and modes of administration to the dog," <i>Journal of Interferon Research</i> , 5:403-408, 1985.
	C21	Giron <i>et al.</i> , "Effect of interferons and poly(I):poly(C) on the pathogenesis of the diabetogenic variant of encephalomyocarditis virus in different mouse strains," <i>J. Interferon Res.</i> , 8(6):745-753, 1988.
	C22	Goldstein <i>et al.</i> , "Human biologic response modification by interferon in the absence of measurable serum concentrations: a comparative trial of subcutaneous and intravenous interferon- β serine," <i>Journal of the National Cancer Institute</i> , 81(14):1061-1068, 1989.
	C23	Goodkin <i>et al.</i> , "Experimental therapies for multiple sclerosis: current status," <i>Cleve. Clin. J. Med.</i> , 59:63-74, 1992.
	C24	Gross <i>et al.</i> , "Interferon- α with condylomata acuminata and juvenile diabetes mellitus," <i>Deutsche Medizinische Wochenschrift</i> , 111(36):1351-1355, 1986. (Abstract)
	C25	Higgins <i>et al.</i> , "Suppression of experimental autoimmune encephalomyelitis by oral administration of myelin basic protein and its fragments," <i>J. Immunol.</i> 140:440-445, 1988.
	C26	Horisberger, "MX protein: function and mechanism of action," <i>Biotechnology</i> , Ciba-Geigy Ltd., CH-4002 Basel, Switzerland.
	C27	Hutchison <i>et al.</i> , "Chronic recurrent aphthous stomatitis: oral treatment with low-dose interferon alpha," <i>Mol. Biother.</i> , 2:160-164, 1990.
	C28	Koech <i>et al.</i> , "Efficacy of Kemron (low dose oral natural human interferon alpha) in the management of HIV-1 infection and acquired immune deficiency syndrome (AIDS)," <i>East Afr. Med. J.</i> , 67(7 Supp 2):SS64-70, 1990.
	C29	Koech <i>et al.</i> , "Low dose oral alpha-interferon therapy for patients seropositive for human immunodeficiency virus type-1 (HIV-1)," <i>Mol. Biother.</i> , 2(2):91-95, 1990.
	C30	Konrad <i>et al.</i> , <i>Biological Barriers to Protein Delivery</i> , ch. 14, 409-437, ed. Audus <i>et al.</i> 1993.
	C31	Larocca <i>et al.</i> , "Evaluation of neutralizing antibodies in patients treated with recombinant interferon- β ser," <i>Journal of Interferon Research</i> , 9(Supp 1):S51-S60, 1989.
✓	C32	Lecce <i>et al.</i> , "Treatment of rotavirus infection in neonate and weanling pigs using natural human interferon alpha," <i>Mol. Biother.</i> 2(4):211-216, 1990.

25503844.1

EXAMINER: /Jegatheesan Seharaseyon/ DATE CONSIDERED: 03/20/2007

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. CLFR:115USC1	Serial No. 10/801,277
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Staley A. Brod	
		Filing Date: March 16, 2004	Group: 1761 1647
U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 1	Other Art See Page 1	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
/JS/	C33	Liu <i>et al.</i> , "Accumulation of protein O-GlcNAc modification inhibits proteasomes in the brain and coincides with neuronal apoptosis in brain areas with high O-GlcNAc metabolism," <i>J. Neurochem.</i> , 89(4):1044-1055.
	C34	Mashkovskii <i>et al.</i> , "Drugs," Moscow, Meditsina, 2:389-392, 1993.
	C35	Mowat <i>et al.</i> , "The regulation of immune responses to dietary protein antigens," <i>Immun. Today</i> , 8:93-98, 1987.
	C36	Nagler <i>et al.</i> , "Immunotherapy with recombinant human interleukin-2 and recombinant interferon-alpha in lymphoma patients postautologous marrow or stem cell transplant," <i>Blood</i> , 89:3951-5959.
	C37	Owens <i>et al.</i> , "The immunology of multiple sclerosis and its animal model, experimental allergic encephalomyelitis," <i>Neurol. Clin.</i> , 13(1):51-73, 1995.
	C38	Paulesu <i>et al.</i> , "Oral administration of human recombinant interferon-a2 in rats," Elsevier Science Publishers B.V. (Biomedical Division), 46:199-202, 1988.
	C39	Radwanski <i>et al.</i> , "Pharmacokinetics of interferon α -2b in healthy volunteers," <i>J Clin Pharmacol</i> , 27:432-435, 1987.
	C40	Satoh <i>et al.</i> , "Suppression of late asthmatic response by low-dose oral administration of interferon-beta in the guinea pig model of asthma," <i>J. Interferon Cytokine Res.</i> , 19:887-894, 1999.
	C41	Schafer <i>et al.</i> , "Interferon administered orally: protection of neonatal mice from lethal virus challenge," <i>Science</i> , 176:1326-1327, 1972.
	C42	Shibutani <i>et al.</i> , "Toxicity studies of human fibroblast interferon beta (I) acute and subacute toxicity studies in mice and rats," <i>Iyakuin Kenkyu</i> , 18:571-582. (1987) (Abstract)
	C43	Shim <i>et al.</i> , "Administration route dependent bioavailability of interferon- α and effect of bile salts on the nasal absorption," <i>Drug Dev. Indus. Pharm.</i> , 19:1183-1199. 1993.
	C44	Thompson <i>et al.</i> , "Gastric administration of type II collagen delays the onset and severity of collagen-induced arthritis in rats," <i>Clin. Exp. Immunol.</i> , 64(3):581-586, 1985.
✓	C45	Vial <i>et al.</i> , "Clinical toxicity of the interferons," <i>Drug Saf.</i> , 10(2):115-150, 1994.
	C46	Wedner <i>et al.</i> , <i>Basic Clinical Immunology</i> , 7 th edition Chap 34, 1991

25503844.1

EXAMINER: /Jegatheesan Seharaseyon/	DATE CONSIDERED: 03/20/2007
EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.	

Form PTO-1449 (modified)		Atty. Docket No. CLFR:115USC1	Serial No. 10/801,277
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Staley A. Brod	
		Filing Date: March 16, 2004	Group: 1761 1647
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
/JS/	C47	Wills <i>et al.</i> , "Pharmacokinetics of recombinant alpha A interferon following IV infusion and bolus, IM, and PO administration to African green monkeys," <i>Journal of Interferon Research</i> , 4(3):399-409, 1984.
↓	C48	Witt <i>et al.</i> , "Absence of biological effects of orally administered interferon-βser," <i>Journal of Interferon Research</i> , 12:411-413, 1992.
↓	C49	Yershov <i>et al.</i> , "Interferon status in different diseases," <i>Voprosy Virusologii</i> , 35:444-448, 1990 (Russian)

25503844.1

EXAMINER: /Jegatheesan Seharaseyon/ DATE CONSIDERED: 03/20/2007

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)